



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/551,408

04/18/2000

Yehuda Ivri

016770-002721US

2446

7590 02/12/2008
TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center
8th Floor
San Francisco, CA 94111-3834

EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/551,408

Applicant(s)

IVRI ET AL.

Examiner

Glenn K. Dawson

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-56 is/are pending in the application.
- 4a) Of the above claim(s) 44-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 07-10-2008
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01-10-2008 has been entered.

Election/Restrictions

Claims 44-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson, et al.-5487378 in view of Abys, et al.-5976344 and/or Marks, et al.-5685491.

1. Robertson discloses a method of aerosolizing a liquid including the steps of electroforming a metal or metal alloy plate (e.g. nickel) to have apertures which taper smaller going from a back surface to the front surface where the droplets will be released; providing liquid at the rear surface of the plate; and vibrating the plate to eject fluid droplets through the apertures. See col. 2 lines 48-64; col. 3 lines 24-52; col. 11 lines 21-23. However, it is not specifically disclosed that the electroformed plate metal is palladium, palladium alloy, palladium nickel or palladium-cobalt. However, Abys discloses that electroplating is a well-known process for providing a coating upon a substrate to improve its resistance to corrosion, abrasion or diffusion. Electroplating is an

efficient process for providing a controlled amount onto a specified area. The bath used to deposit the alloy on the substrate is versatile enough to deposit alloy compositions with between 10%-95% palladium. Palladium has been plated over nickel to provide a low contact resistance and corrosion resistance. Palladium-nickel alloy increases hardness, corrosion resistance and wearability, whereas palladium-cobalt improves hardness, corrosion resistance and reduces allergenic effects. It is also known that the thickness of the plating may vary depending on the application or need and availability of product. In fact if cost is not a significant factor it is also considered to be obvious to form most of the plate out of these materials while reducing the size of the substrate in order to maximize the effectiveness of the plate.

2. It would have been obvious to have made the vibrating plate of Robertson by electroforming the plate out of palladium, palladium-nickel or palladium-cobalt, instead of just nickel, as a matter of design choice, as it would enhance the corrosion resistance of the plate and therefore prevent degradation due to contact with the liquid drug applied thereto, and would provide a plate with improved hardness, and in some cases allergenic effects. In fact the applicant has failed to disclose any criticality as to the materials of the plate being palladium or palladium alloy, palladium nickel or palladium

cobalt and alone would be an obvious design choice as the examiner considers that the prior art materials would work equally as well as that disclosed by the applicant.

3. The specific percentage of palladium to nickel is considered to be an obvious design choice known to one skilled in the art in that the advantages of both materials would be realized by minimizing the possible allergenic effects due to the presence of the nickel component.

4. Marks discloses a method of forming an apertured plate having spray nozzles for any type of apparatus where atomization and flow control are desired, whereby a substrate of materials listed in col. 5 lines 27-30 is electroformed with nickel, gold, palladium and alloys thereof to form an apertured electroformed plate with spray orifices. (see col. 8 line 47 – col. 9 line 10 for the manufacturing method).

5. It would have been obvious to have formed the apertured spray plate of Robertson with the materials taught by Marks, as these materials are known to provide durability and corrosion resistance and as such would have been obvious design choices to provide for increased use and to prevent degradation due to contact with the liquid drug applied thereto. In fact the

applicant has failed to disclose any criticality as to the materials of the plate being palladium or palladium alloy, palladium nickel or palladium cobalt and alone would be an obvious design choice as the examiner considers that the prior art materials would work equally as well as that disclosed by the applicant. The specific percentage of palladium to nickel is considered to be an obvious design choice known to one skilled in the art in that the advantages of both materials would be realized by minimizing the possible allergenic effects due to the presence of the nickel component.

Response to Arguments

Applicant's arguments filed 11-08-2007 have been fully considered but they are not persuasive.

The base reference to Robertson teaches of electroforming a plate having the claimed tapered apertures. Therefore, the only missing element is the material from which the plate is made. As the plate material is clearly not a new concept in these aerosolization plates, as evidenced by Abys and Marks, electroforming a tapered-aperture plate using the claimed materials would have been obvious. Applicant argues that it would not be obvious to exchange the material of Robertson's plate with palladium etc. simply because the

teaching references show that such materials were known in the electro-deposition art. The examiner has identified reasons why the claimed materials would be obvious alternative materials for the plate used by Robertson... durability, hardness, reduced allergenic effects and corrosion resistance. The applicant, on the other hand, makes a statement that the claimed materials offer unobvious advantages, but fails to point out what these advantages are, or where in the specification these advantages are disclosed. Absent any criticality, the examiner contends that the proffered exchange of plate materials is nothing more than an obvious design choice and exchange of known alternatives. Applicant states that Robertson teaches away from any material other than nickel because the disclosure is limited to nickel. This argument is not persuasive. Unless a disclosure alludes to other non-disclosed materials as being undesirable or unusable for specific reasons, or why the only disclosed material can be used for specific reasons, the lack of a disclosure of other materials is not a teaching away of other materials. In actuality, Robertson also discloses that silicon, germanium or plastic material can also be employed (see col. 3 lines 14-36). This hardly teaches away from the use of other materials. One of skill in the art would have had every reason to have expected success in producing a vibration plate having utility in the

field of applicant's invention and the prior art when making the proposed combination and exchange of known materials. Exchanging the metals for the plate would have produced a predictable result of an electroformed plate usable for the intended use of aerosolizing a medicinal substance and would produce a plate with the advantages of the palladium alloys noted above. It is a mere substitution of one known element for another known element to obtain these predictable results. Choosing palladium or a palladium alloy would have been obvious to try as it would be one of a finite number of identifiable materials which would have been predictable solutions for choosing a material capable of being electroformed into such a drug aerosolization vibration plate.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
04 February 2008

/Glenn K Dawson/
Primary Examiner, Art Unit 3731